K053289

AUG 10 2006

510(k) Summary – COBAS AMPLICOR CT/NG test for Neisseria gonorrhoeae with Roche Scripts Accessory

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence

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Submitter name, address, contact

Roche Diagnostics
9115 Hague Rd
Indianapolis IN 46250
(317) 521-3723

Contact person: Theresa M. Ambrose

Date prepared: November 22, 2005

Device Name

Proprietary Name: COBAS AMPLICOR CT/NG test for *Neisseria gonorrhoeae;* Roche Scripts for COBAS AMPLICOR CT/NG Test (Roche Scripts Accessory)

Common name: Neisseria gonorrhoeae test system ; software accessory

Classification name: DNA reagents, Neisseria

Device Description

The COBAS AMPLICOR CT/NG test for *Neisseria gonorrhoeae* is a qualitative in vitro test for the detection of *N. gonorrhoeae* DNA in urine from symptomatic or asymptomatic males, in endocervical swab specimens from symptomatic or asymptomatic females, and in urethral swab specimens from symptomatic males as evidence infection with *N. gonorrhoeae. N. gonorrhoeae* DNA is detected by Polymerase Chain Reaction (PCR) amplification of target DNA and by hybridization capture of amplified target using the COBAS AMPLICOR analyzer.

The Roche Scripts for COBAS AMPLICOR CT/NG Test accessory consists of a compact disc (CD) containing software scripts which direct the automated Tecan Genesis RSP 150 Workstation to process swab samples or control material for analysis.

Continued on next page

510(k) Summary, Continued

Intended use

The COBAS AMPLICOR CT/NG test for *Neisseria gonorrhoeae* is a qualitative in vitro test for the detection of *N. gonorrhoeae* DNA in urine from symptomatic or asymptomatic males, in endocervical swab specimens from symptomatic or asymptomatic females, and in urethral swab specimens from symptomatic males as evidence infection with *N. gonorrhoeae. N. gonorrhoeae* DNA is detected by Polymerase Chain Reaction (PCR) amplification of target DNA and by hybridization capture of amplified target using the COBAS AMPLICOR analyzer.

The Roche Scripts for COBAS AMPLICOR CT/NG Test are intended to provide software scripts to direct the automated Tecan Genesis RSP 150 Workstation to process swab samples or control material for analysis using either of the following 510(k)-cleared assay test systems:

- COBAS AMPLICOR™ CT/NG test for Chlamydia trachomatis
- COBAS AMPLICOR™ CT/NG test for Neisseria gonorrhoeae

Predicate Device

We claim equivalence to the currently marketed COBAS AMPLICOR CT/NG test for *Neisseria gonorrhoeae* cleared under K974342.

Comparison - similarities

The table below shows the similarities between the COBAS AMPLICOR CT/NG test for *Neisseria gonorrhoeae* with optional Roche Scripts accessory and the predicate device:

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Theresa M. Ambrose Bush, Ph.D., RAC
Regulatory Affairs Principal
Centralized Diagnostics
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50416
Indianapolis, Indiana 46256-0416

AUG 10 2006

Re: k053289
Trade/Device Name: Roche Scripts for COBAS AMPLICOR CT/NG Test
Regulation Number: 21 CFR § 866.3390
Regulation Name: Direct Serological Test Reagents
Regulatory Class: II
Product Code: LSL
Dated: June 30, 2006
Received: July 3, 2006

Dear Dr. Ambrose Bush:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

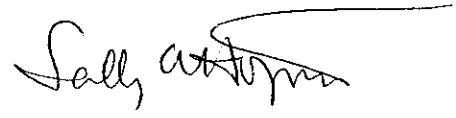
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240)276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053289

Device Name: Roche Scripts for COBAS AMPLICOR CT/NG Test

Indications For Use:

The Roche Scripts for COBAS AMPLICOR CT/NG Test are intended to provide software scripts to direct the automated Tecan Genesis RSP 150 Workstation to process swab samples or control material for analysis using either of the following 510(k)-cleared assay test systems:

- COBAS AMPLICOR™ CT/NG test for Chlamydia trachomatis
- COBAS AMPLICOR™ CT/NG test for Neisseria gonorrhoeae

Prescription Use **XXXX** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K053289